



May 17, 2013

The Honorable Frederick Stephen Upton
Chairman
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, D.C. 20515

The Honorable John Boehner
Office of the Speaker
H-232 The Capitol
Washington, D.C. 20515

Letter in Support of H.R. 1919: Safeguarding America's Pharmaceuticals Act

Dear Speaker Boehner and Chairman Upton:

On behalf of the Pharmaceutical Security Institute (PSI), I write in strong support of H.R. 1919, the "Safeguarding America's Pharmaceuticals Act."

PSI is an international nonprofit membership organization dedicated to protecting the public health, sharing information on pharmaceutical crime, and initiating law enforcement actions through the appropriate authorities. PSI-supported investigations and enforcement actions have successfully neutralized sizable pharmaceutical counterfeiting operations.

PSI vigorously supports the creation of a national uniform, national track and trace or pedigree system to electronically monitor the distribution of finished prescription drugs in the domestic supply chain. This system would allow all supply chain participants to protect the integrity of the products and avoid illegal activities such as diversion and counterfeiting.

Pharmaceutical crime continues to be a significant public health threat in the United States. Every day, many people unknowingly consume medicines that may be unsafe, ineffective or both due to unscrupulous individuals who profit by exploiting the vulnerabilities of the legitimate supply chain. PSI recorded almost 10,000 worldwide incidents of counterfeiting, diversion and major theft over the last five years, 940 of those occurring in the United States. It is crucial that we accelerate our efforts to reduce the risk of illegal pharmaceuticals entering the supply chain and protect critical programs like Medicaid and Medicare from fraud schemes by implementing a national serialization and verification system.

Recent events show the need for a nationwide system to certify the origin of pharmaceuticals and track their whereabouts. For instance, in a single December 2012 incident, members of a criminal enterprise accused of generating \$650 million in ill-gotten gains by selling prescription drugs not approved by the U.S. Food and Drug

Administration (FDA) were indicted in Puerto Rico, in one of the largest cases to date. These drugs were sold between 2007 and 2011 to chain and independent pharmacies in cities such as Detroit, New York, Miami and Los Angeles. Seized evidence showed that the drugs were expired and had counterfeit labels, some with incorrect dosages. Some of these counterfeit drugs were acquired by chain pharmacies in the District of Columbia and Arizona, submitting fake pedigree documents to the pharmacies that bought the drugs. Key to the success of this criminal scheme was the use of pedigrees falsely stating that the drugs were obtained from authorized distributors when they actually originated from a network of unlicensed suppliers based mostly in California and New York. The ease and scale of the penetration of counterfeit drugs into the legitimate supply chain in this case clearly demonstrates that new comprehensive measures are required to ensure the integrity of the supply chain. An initiative to develop the serialization and tracking of product packages, such as a track and trace program, could prevent this criminal activity by impeding, to a large extent, the use of fake packaging and pedigrees.

Your bill, H.R. 1919, would require the FDA to propose new rules to develop a prescription drug track and trace system. Expanding the FDA authority over of the supply chain through a technology that allows the easy verification of the origin of prescription drugs through a unique identifier will bring a uniform standard and prevent any serious breaches. This bill would also mandate supply chain participants to disclose transaction history and provide a transaction statement. Further, by creating minimum national standards for the licensing of wholesale distributors, your bill will help to ensure that only qualified and law-abiding parties engage in this vital line of business.

PSI greatly appreciates your ongoing leadership in securing the pharmaceutical supply chain. We are pleased you have championed such legislation that protects the quality, effectiveness and safety of the pharmaceuticals dispensed in the United States. We look forward to working with you to advance our mutual goal of improving health care for all Americans.

Respectfully submitted,

Thomas T. Kubic
President & CEO
The Pharmaceutical Security Institute, Inc.